MAR - 5 2001

Mentor Self-Cath® Plus
510(k) Notification

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: K003784

Contact Person: Donna A. Crawford
Director, Corporate Regulatory Affairs
Mentor Corporation
201 Mentor Drive
Santa Barbara, CA 93111

Telephone: 805-879-6304
FAX: 805-879-6015

Date Prepared: December 5, 2000

Device Name and Classification

Proprietary Name: Mentor Self-Cath® Plus

Common Name: Intermittent Urethral Urinary Catheter

Classification Name: Urological Catheter and Accessories

Product Code: Unknown

Manufacturer

Mentor Urology
1601 West River Road North
Minneapolis, MN 55411

Device Description

The Mentor Self-Cath® Plus Intermittent Urethral Urinary Catheter is intended for use as a sterile, single use urinary catheter for intermittent catheterization.

Substantial Equivalence Claim

The Mentor Self-Cath® Plus Intermittent Urethral Urinary Catheter is substantially equivalent to pre-amendment devices and intermittent catheters manufactured by Mentor and to the Astra Medical LoFric® Urethral Urinary Catheter.

Indications for Use

The Mentor Self-Cath® Plus catheter is intended for use in male, female, and pediatric patients requiring bladder drainage as determined by their physician. This device is indicated for those individuals unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.

Summary of Testing

Mentor has performed full device biocompatibility testing. The Mentor Self-Cath® Plus catheter product passed the *In Vitro* biocompatibility testing for Ames Mutagenicity and Iso Elution, and *In Vivo* biocompatibility testing for USP Mouse Systemic, Maximization and Vaginal Mucous Irritation at NamSa, Inc.

Note: The material components of the Self-Cath® Plus catheter are unchanged from the Self-Cath® catheter except that the silicone coating is replaced by the PVP coating. Full device testing has been performed to ensure the biocompatibility of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 2001

Ms. Donna A. Crawford
Director, Corporate Regulatory Affairs
Mentor Corporation
201 Mentor Drive
SANTA BARBARA CA 93111

Re: K003784
Mentor Self-Cath® Plus Intermittent
Urethral Urinary Catheter
Dated: December 5, 2000
Received: December 7, 2000
Regulatory Class: II
21 CFR §876.5130/Procode: 78 EZL

Dear Ms. Crawford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Mentor Self-Cath® Plus
510(k) Notification

510(k) Number (if known): K003784

Device Name: Mentor Self-Cath® Plus

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003784